

LAW OFFICES
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20037-3202

TELEPHONE (202) 293-7060

TELEX
6491103

FACSIMILE
(202) 293-7860
(202) 293-9131
(202) 293-2920

September 11, 1998

BOX PATENT APPLICATION
ASSISTANT COMMISSIONER OF PATENTS
Washington, D.C. 20231

Re: Application of JOHN KIRCHGEORG and RICHARD C. TURNER
PORTABLE EMERGENCY OXYGEN AND AUTOMATIC EXTERNAL
DEFIBRILLATOR (AED) THERAPY SYSTEM
Our Ref: A7205

Dear Sir:

Attached hereto is the application identified above including the specification, claims, and four (4) sheets of drawings, **executed Assignment, Filing Fee, Small Entity Declaration and Declaration and Power of Attorney will be submitted later.**

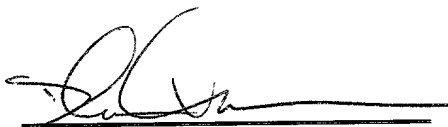
The Government filing fee is calculated as follows:

Independent Claims	5	-	3	=	2	x	\$41.00	=	\$	82.00
Total Claims	26	-	20	=	6	x	\$11.00	=	\$	66.00
Base Fee									\$	395.00
Multiple Dependent Claim Fee (\$270.00)									\$	0.00
TOTAL FILING FEE									\$	543.00

A check for the statutory filing fee of \$543.00 will follow. Except for the payment of this filing fee, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 and any petitions for extension of time under 37 C.F.R. § 1.136 which may be required during the entire pendency of the application to Deposit Account No. 19-4880. A duplicate copy of this transmittal letter is attached.

There is no claim to priority.

Respectfully submitted,
SUGHRUE, MION, ZINN,
MACPEAK & SEAS, PLLC


Richard C. Turner
Registration No. 29,710

09/11/98
jc518 U.S. PTO

jc518 U.S. PTO
09/15/00
09/11/98

09/11/98 09/15/00

**PORTABLE EMERGENCY OXYGEN AND AUTOMATIC EXTERNAL
DEFIBRILLATOR (AED) THERAPY SYSTEM**

5

BACKGROUND OF THE INVENTION

1. Field of the Invention

10

The present invention relates to an emergency medical diagnosis and therapy system integrating several emergency medical equipment components into a single multi-functional unit within a convenient unitary casing, so that medical personnel can easily handle, access and implement a variety of important emergency tools and therapies.

2. Description of the Related Art

Conventional emergency medical equipment has been improved over the years to advance the ability of emergency medical personnel to administer vital care to patients. Such advancements include voice prompting, automated and individualized patient assessments and self-maintenance of the equipment.

25

for example, a variety of small, portable on-site devices are available for administering electric pulse therapy in emergency situations of myocardial infarction and to defibrillate and restart regular heart pump rhythms necessary for sustaining the life of the patient. Most of these Automatic External Defibrillator (AED) devices include electro-cardio diagnosis and monitoring of the patient, and many include voice prompting for the user. There are also known O₂ and CO oximetry

30

devices for measuring arterial oxygenation, perfusion, O₂Hb dissociation, tissue O₂ affinity, O₂ content, PO₂, pulse oximetry saturation (SPO₂), or calculated oxygen saturation (%SO₂), because oxygen supplementation is critical in many emergency cardiopulmonary trauma situations. For this latter purpose, there exist a wide variety of oxygen resuscitators, inhalators, or ventilators.

Often, first responder medical personnel have arrived on site to attend the victim with an AED defibrillator, but have been unable to resuscitate and keep alive the victim without supplemental oxygen on hand. In many instances the victim was successfully defibrillated, but poor cell perfusion and toxic gases due to hypoxia prevented successful recovery. In many other instances, the first responder arrived when the vital signs of the victim were declining but could do little until after the victim had begun fibrillation or expired. In the first instances, supplemental oxygen administration may have insured successful survival of the defibrillated victim. In the second instances, supplemental oxygen administration may have even precluded the need for the defibrillator. In both instances, emergency oxygen may have saved the victim by restoring the proper oxygenation and cell perfusion necessary for survival.

Heretofore, each piece of emergency equipment has typically been contained in its own housing or carrying case and used independently, as a stand-alone unit. Handling each piece of equipment separately, however, is inconvenient and cumbersome for medical personnel, who are often situated in awkward conditions and dangerous circumstances, such as at automobile accident

sites. Moreover, the use of separate units ignores the interdependence of administration among the several emergency systems.

SUMMARY OF THE INVENTION

Accordingly, the present invention improves upon conventional arrangements by providing a medical care system comprising a plurality of interdependent emergency medical systems in one convenient unit.

An object of the invention is to provide a multifunctional emergency medical care system which places a plurality of interdependent emergency therapy devices in a single unit, and which is capable of guiding emergency medical personnel through emergency procedures which employ these devices simultaneously.

A further object of the invention is to provide an emergency medical therapy system having various devices which may be needed in a medical emergency, arranged in a housing unit in a manner allowing easy and convenient simultaneous access to each piece of equipment so that the user can utilize the equipment easily, quickly and efficiently.

Additional features and advantages of the invention will be set forth in the description which follows, and in part will be apparent from the description, or may be learned by practice of the invention. The objectives and other advantages of the invention will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and together with the description serve to explain the principles of the invention.

In the drawings:

Fig. 1 is a perspective view illustrating a first embodiment of the system;

Figs. 2 and 3 are perspective views illustrating variations of the embodiment of the system, and

Fig. 4 is a system diagram of a fully integrated emergency medical system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to the preferred embodiments of the present invention, examples of which are illustrated in the accompanying drawings.

Referring to Fig. 1, the first embodiment illustrates a housing 1 having two access openings for accessing two compartments 20, 30. Two clear or opaque covers 10, 12 cover the openings, respectively.

Handle 40 provides a means for carrying the unit to a victim or patient. This allows the user to have a free hand for other equipment, handling a patient or other important tasks. Moreover, with multiple pieces of equipment housed in the same unit, the user needs to only look at the face of the unit to view the various displays for the different systems.

Thus, consolidating multiple medical devices into one unit provides easier handling and convenience for the user.

A convenient variation is illustrated in Fig. 2. Instead of having two covers, this embodiment has one cover 14 for covering the openings of compartments 20, 30. In this embodiment, only a single cover 14 is removed to access the various compartments of the housing 1.

This provides an advantage over the first embodiment since the user only needs to remove a single cover to access all the equipment. During an emergency, when time is of the essence, this provides an important advantage for the user of saving time. The rest of this variation is similar to the first embodiment and thus, the features are represented by the same reference numerals and a detailed description is omitted.

Fig. 3 illustrates another variant of the invention. A single cover 16 covers the entire front face of the housing 1. Thus, all the equipment pieces, including the displays and controls are covered with a preferably clear cover 16.

This variation provides an advantage over the first and second described in units in that the displays 80, speaker 50, and other various controls 60 are protected by the cover 16. Thus, during use the operator only needs to remove a single cover piece to access all components in the housing. After use, the single cover protects all the controls and displays, as well as the other equipment housed in the compartments from damage during storage or transport.

As noted above, each compartment 20, 30 holds one or more emergency medical devices. Several component variations are

possible. For instance, the housing may combine a small-sized emergency oxygen unit (gas dispensing device) with an oximeter, a pulse display and electrode lead. As another alternative, either or both of the emergency oxygen unit and oximetry system may be combined with an Automatic External Defibrillator (AED), corresponding controls and paddle electrodes. In either case, the system may include a voice prompt system, selection controls and a speaker. Many other combinations are possible, as will be evident to those of skill in the art.

Fig. 1 shows housing 1 having a gas dispensing device 70 and an electrocardio defibrillation device 75, the former comprising an oxygen cylinder with a mechanical or electromechanically controlled regulator, gauge, mask and hose in one compartment 20.

The oxygen dispensing device may be functional in two modes: manual mode, in which an on/off switch or lever simply controls on/off supply of oxygen, generally delivered at a fixed or variable low flow rate, or automatic mode, where the flow rate is variable and may be controlled either according to program control or via feedback from the oximetry unit. Included within the variable flow rate mode may be a ventilation mode for non-breathing victims, wherein liter flow and pressure are subjected to time sequencing according to a cycle corresponding closely to requirements the victim needs to return to a normal breathing pattern. Compartment 30 stores defibrillator shock paddle electrodes 121 and oximeter electrode 107. Several other component variations are also possible.

The defibrillation device and associated controls are contained entirely within the housing 1, and may be of a form

known in the art, as represented by U.S. Patents 5,797,969, 5,792,190, 5,749,902, 5,700,281, 5,716,380, 5,605,150, 5,549,659, 5,529,063, 5,243,975, 5,785,043, 5,782,878, 5,749,913 and 5,662,690, each of which is incorporated by reference herein.

5 Several of these known defibrillators include voice prompting; the invention deviates from the known voice prompting scheme in that it also includes timely prompts for oximetry measurement and the administration of oxygen. The protocols for the coordination of oximetry, oxygen administration and defibrillation are known generally in the medical arts, and therefore will not be explained in detail here.

10 Housing 1 holds power source 90 (battery), and the known controls 110, 103 and displays 116, 118 for the defibrillator and oximeter. A speaker 50 is also housed in the housing 1, to be used in conjunction with voice prompting tools and controls 113.

15 An example of the use of the invention will now be described, in order to better explain the functionality of the invention.

20 At an accident scene, for example, it is determined that a victim is currently in cardiac arrest. Upon enabling the unit of the invention, controls 113 may be activated to enable the voice prompt system, which will guide the user through the steps necessary to operate the oxygen delivery, oximetry and defibrillation systems. Such voice prompt systems are known in the portable defibrillation arts, however, according to the invention the prior art system may be modified to include prompts for effecting oxygen administration and oximetry measurements.

25

For example, in this example of a non-breathing victim in cardiac arrest, the voice prompt system may guide the user through the following protocols:

- initiate and deploy defibrillation system and paddles
- administer electroshock treatment
- initiate oxygen delivery in ventilator mode
- deploy oximetry measuring electrode.

If the defibrillation is successful, as determined by a pulse reading, the voice prompt system may subsequently guide the user through switching of the ventilator mode to a regulated constant volume oxygen delivery mode which is more suitable for a breathing patient, and/or make other variations in oxygen delivery via program control or in response to oximetry readings. Naturally, many variations are possible as will be readily apparent to those of skill in the art.

In its most simple form, the integrated emergency medical systems of the invention may be substantially without interdependent control. For example, an emergency oxygen device can be combined with a defibrillation system, without any electromechanical connection therebetween. In such a case, if voice prompting is added, the system may prompt only for defibrillation, or both defibrillation and oxygen delivery, for example.

A more integrated and sophisticated system is illustrated in Fig. 4. In this system, a control processor controls operation of the various emergency medical units (oxygen delivery, defibrillation and oximetry), accepts feedback from each of these units, interfaces with and controls the voice

prompt system, and drives the various displays 116, 118. When the operator selects AED or oximetry functions by operating inputs 103 110, the processor controls defibrillator control 111 to generate an output waveform of a selected type in accordance with operator selection, and controls oximetry control section 102 in accordance with operator selection to perform various measurements and drives display 116 to display these measurements, e.g., pulse rate and blood O₂ related measurements, to the operator in real time. Similarly, processor 101 drives LCD screen 118 to display user instructions and prompts, respiratory monitoring and diagnosis, and cardio diagnosis and monitoring data.

Processor 101 also interfaces with voice prompt system 112 to cause the latter to deliver a selected sequence of voice prompts via speaker 114 according to predetermined protocols, operator input and the condition of the patient as measured by the system, including sensors 107, in a manner generally similar to that known in the art.

As noted previously, the oxygen delivery system 105 can be controlled either manually or by automatic control. In a manual mode, for example, the system 105 may deliver oxygen at a fixed liter flow and pressure, or at a plurality of flow rates. In automatic mode, the system 105 may, in response to a control signal from processor 101 (or user input), deliver a time sequenced flow rate and pressure to operate as a ventilator. In response to user input, a control signal from processor 101 or feedback from oximetry control 102, the system 105 can be switched from ventilator mode to fixed flow rate mode, the latter

being more suitable for patients capable of breathing on their own. Other fixed or variable flow rates may be elected via control signals from processor 101 or feedback from oximetry control 102

5 With the present invention, a single therapy unit can combine emergency cardiac defibrillation and pulmonary oxygen administration in one convenient casing. An electrocardio diagnosis/monitoring/defibrillation device can be combined with electropulmonary blood oximetry/oxygen administration, including
10 automated patient cardio-pulmonary oxygen assessment and voice prompted therapy and resuscitation.

Although described herein as an interactive combination of oxygen delivery, oximetry and defibrillation systems, it will be apparent that the invention could be comprised of a combination of any two of these systems, with associated modification of the control mechanisms and voice prompts, as will be evident to those
15 of skill in the art.

What Is Claimed Is:

1. A plurality of medical devices combined in a unitary housing, comprising:

an outer casing having at least one opening for accessing at least one compartment within the housing;

at least one cover for covering said opening(s),

wherein said compartment(s) hold a gas dispensing device and additional medical equipment.

2. A plurality of medical devices combined in a unitary housing, comprising:

an outer casing having a first and a second opening for accessing a first and a second compartment within the housing;

a first cover for covering said first opening and a second cover for covering said second opening,

wherein said first compartment holds a gas dispensing device and said second compartment holds additional medical equipment.

3. A plurality of medical devices combined in a unitary housing, comprising:

an outer casing having a first and a second opening for accessing a first and a second compartment within the housing;

a cover for covering one side of said outer casing, including said first and second opening,

wherein said first compartment holds a gas dispensing device and said second compartment holds additional medical equipment.

4. The system according to claim 1, wherein said compartment(s) hold an oximeter electrode and the housing further comprises a display panel.

5. The system according to claim 2, wherein said second compartment holds an oximeter electrode and the housing further comprises a display panel.

6. The system according to claim 3, wherein said second compartment holds an oximeter electrode and the housing further comprises a display panel.

7. The system according to claim 4, further comprising an automatic external defibrillator and shock paddle electrodes, said compartment(s) holding said shock paddle electrodes for said automatic external defibrillator.

8. The system according to claim 5, further comprising an automatic external defibrillator and shock paddle electrodes, said second compartment holding said shock paddle electrodes for said automatic external defibrillator.

9. The system according to claim 6, further comprising an automatic external defibrillator and shock paddle electrodes, said second compartment holding said shock paddle electrodes for said automatic external defibrillator.

10. The system according to claim 7, further comprising a control panel including voice prompt selection/controls, automatic external defibrillator controls, and oximeter controls.

11. The system according to claim 8, further comprising a control panel including voice prompt selection/controls, automatic external defibrillator controls, and oximeter controls.

12. The system according to claim 9, further comprising a control panel including voice prompt selection/controls, automatic external defibrillator controls, and oximeter controls.

13. The system according to claim 3, wherein said cover covers said control panel.

14. The system according to claim 1, wherein said cover is clear for viewing the medical equipment within said compartment(s) while said cover is positioned over said opening(s).

15. The system according to claim 2, wherein said cover is clear for viewing the medical equipment within said first and second compartments while said cover is positioned over said first and second openings.

16. The system according to claim 14, wherein said cover is clear for viewing the medical equipment within said compartment(s) and said control panel while said cover(s) are positioned over said housing.

17. A multi-component emergency medical system, comprising;
an oxygen delivery system;
a defibrillation system; and
a unitary casing for housing said oxygen delivery system and
said defibrillation system.

18. A multi-component emergency medical system, comprising;
an oxygen delivery system;
an oximetry system;
a defibrillation system; and
a unitary casing for housing said oxygen delivery system,
said oximetry system and said defibrillation system.

19. A system as claimed in claim 18, further comprising a voice
prompting system for directing a user through a protocol
employing said defibrillation system.

20. A system as claimed in claim 18, further comprising a voice
prompting system for directing a user through a protocol
employing said defibrillation system and said oxygen delivery
system.

21. A system as claimed in claim 18, further comprising a voice
prompting system for directing a user through a protocol
employing said defibrillation system, said oxygen delivery system
and said oximetry system.

22. A system as claimed in claim 21, further comprising a control processor for controlling operations of at least said defibrillation system, said voice prompting system and said oximetry system.

23. A system as claimed in claim 22, wherein said control processor further controls said oxygen delivery system.

24. A system as claimed in claim 23, further comprising a feedback control from said oximetry system to said oxygen delivery system.

25. A system as claimed in claim 24, further including a display system coupled to said oximetry system.

26. A system as claimed in claim 24, further including means for modal control of said oxygen delivery system, for switching or prompting a user to switch said oxygen delivery system between a variable flow rate/pressure cyclic ventilator mode and a fixed flow rate mode.

ABSTRACT OF THE DISCLOSURE

This invention provides a medical diagnosis and therapy system particularly adapted for the combined uses of emergency cardiac defibrillation and pulmonary oxygen administration, including automated patient cardio-pulmonary assessment and voice prompted therapy and resuscitation: electrocardio diagnosis/monitoring/defibrillation and electropulmonary blood oximetry/oxygen administration. The system has a case having access opening(s) and clear cover(s) to view the apparatus and contents, to dispel all doubt as to know how to open the case and to make it easy for a user to quickly find and use the various components.

STORAGE AREA FOR:
AED SHOCK PAD/LE ELECTRODES
AND OXIMETER ELECTRODE
(NONE SHOWN FOR CLARITY)

OXYGEN CYLINDER,
REGULATOR, GAUGE,
MASK AND HOSE
(MASK AND HOSE
NOT SHOWN
FOR CLARITY)

REAR STORAGE AREA 90
FOR DC BATTERY,
(TERMINAL WIRES IN
BACK COMPARTMENT)

OXYGEN AND
PULSE DISPLAY 116
FOR OXIMETER

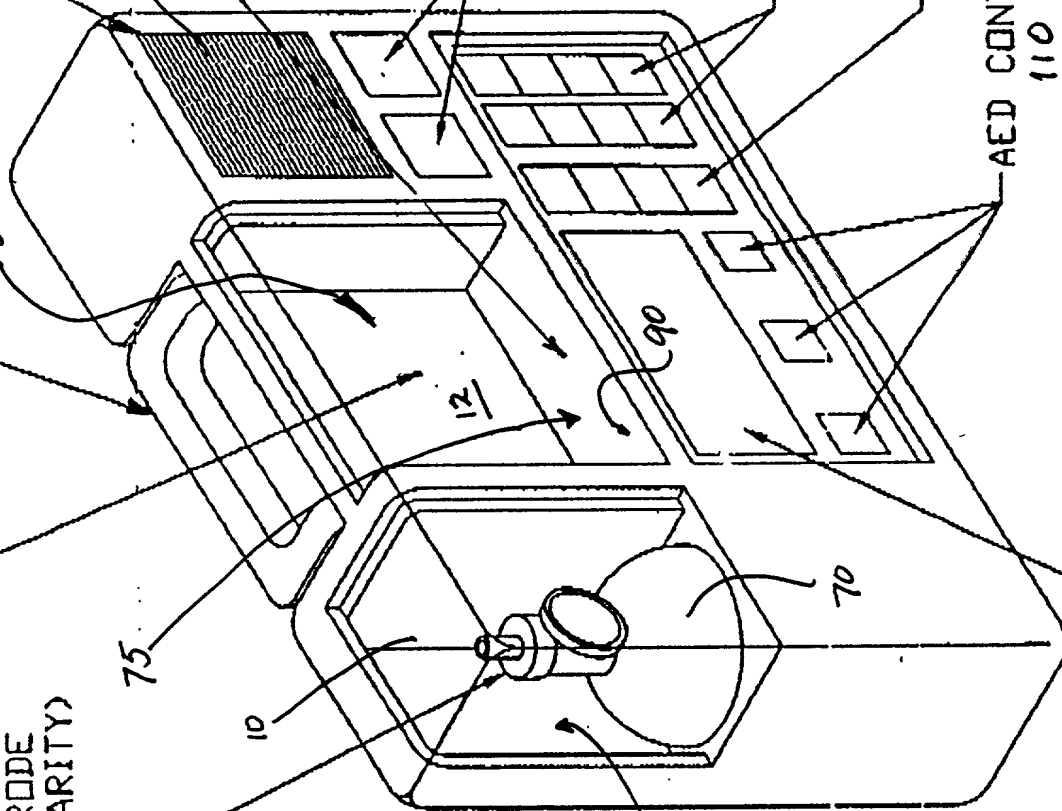
VOICEPROMPT
SELECTION/CONTROLS
113

OXIMETER CONTROLS 103

AED CONTROLS
110

7-LCD SCREEN 118

Fig. 1



23.5" DEPT HANDLE

STORAGE AREA FOR:
AED SHOCK PAD/ELE ELECTRODES
AND OXIMETER ELECTRODE
(NONE SHOWN FOR CLARITY)

OXYGEN CYLINDER,
REGULATOR, GAUGE,
MASK AND HOSE
(MASK AND HOSE
NOT SHOWN
FOR CLARITY)

REAR STORAGE AREA
FOR DC BATTERY,
(TERMINAL WIRES IN
BACK COMPARTMENT)

OXYGEN AND
PULSE DISPLAY
FOR OXIMETER

VOICEPROMPT
SELECTION/CONTROLS

OXIMETER CONTROLS

AED CONTROLS

LCD SCREEN

Fig. 2



STORAGE AREA FOR:
AED SHOCK PADDLE ELECTRODES
AND OXIMETER ELECTRODE
(NONE SHOWN FOR CLARITY)

OXYGEN CYLINDER,
REGULATOR, GAUGE,
MASK AND HOSE
(MASK AND HOSE
NOT SHOWN
FOR CLARITY)

ALSO NOT SHOWN:
ELECTRO-MECHANICAL ON/OFF,
LITER FLOW-CONTROL, AND
PRESSURE CONTROL, AND
LITER FLOW/PRESSURE/TIME
SEQUENCING (VENTILATOR)

HANDLE

SPEAKER

REAR STORAGE AREA
FOR DC BATTERY,
(TERMINAL WIRES IN
BACK COMPARTMENT)

OXYGEN AND
PULSE DISPLAY
FOR OXIMETER

VOICEPROMPT
SELECTION/CONTROLS

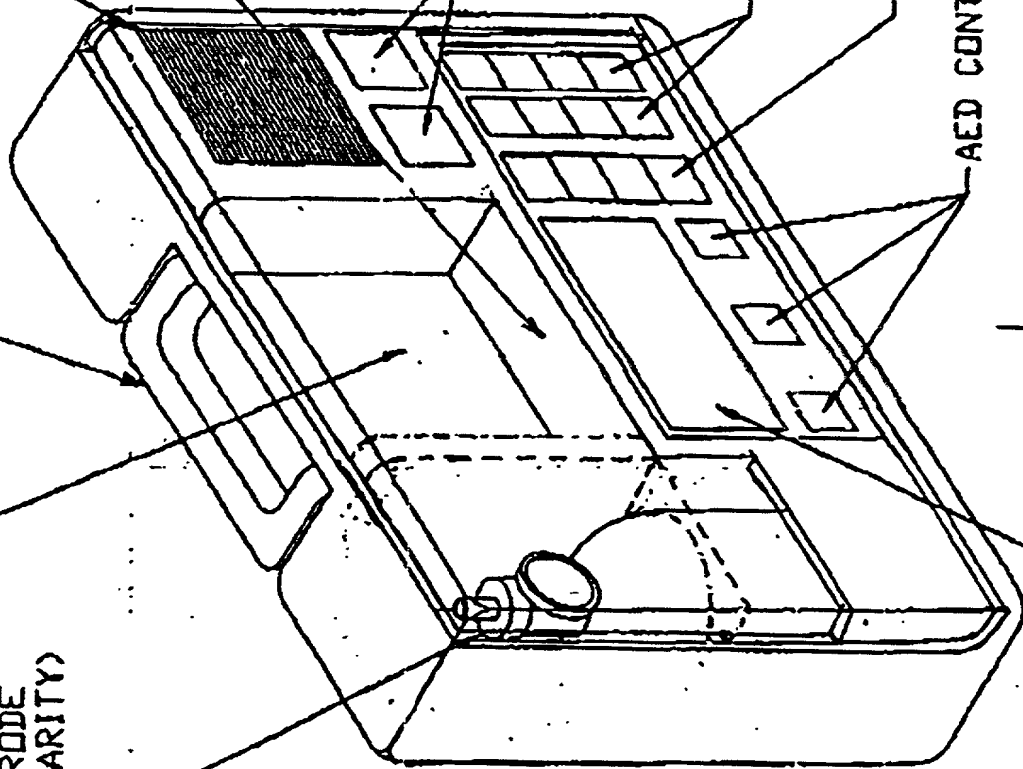
OXIMETER CONTROLS

AED CONTROLS

LCD SCREEN

- CARDIO-DIAGNOSIS & MONITORING
- RESPIRATORY DIAGNOSIS & MONITORING
- USER INSTRUCTIONS & PROMPTS

Fig. 3



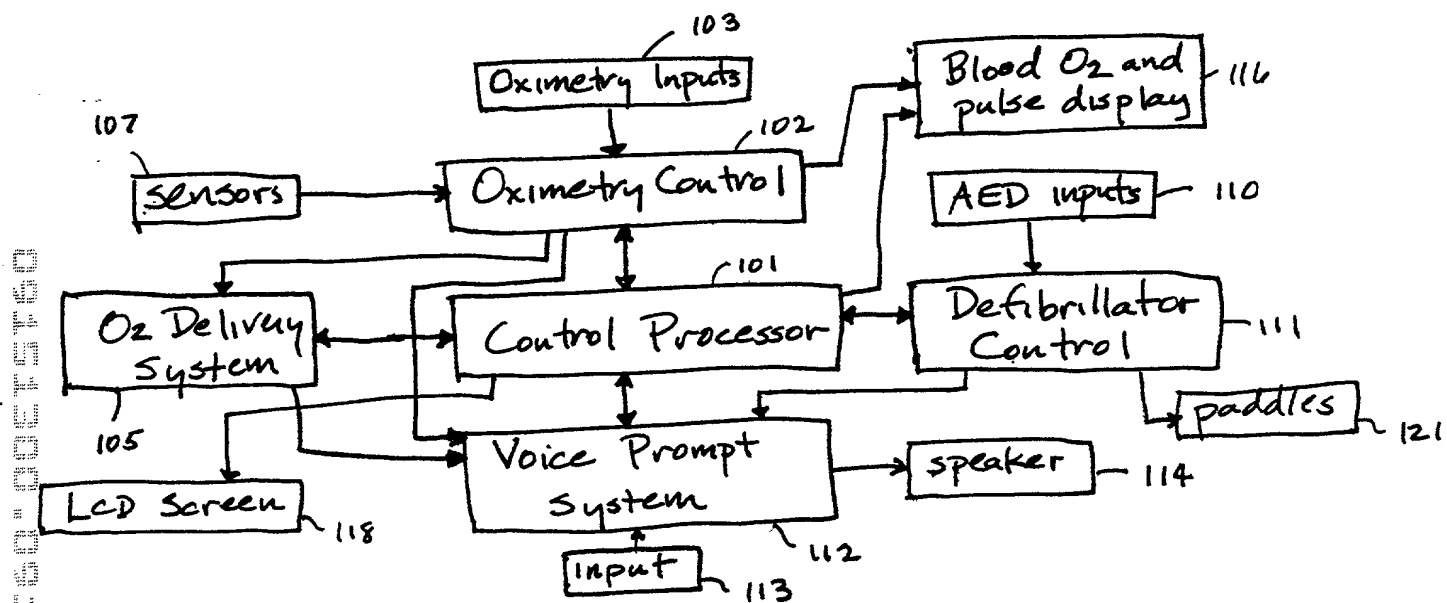
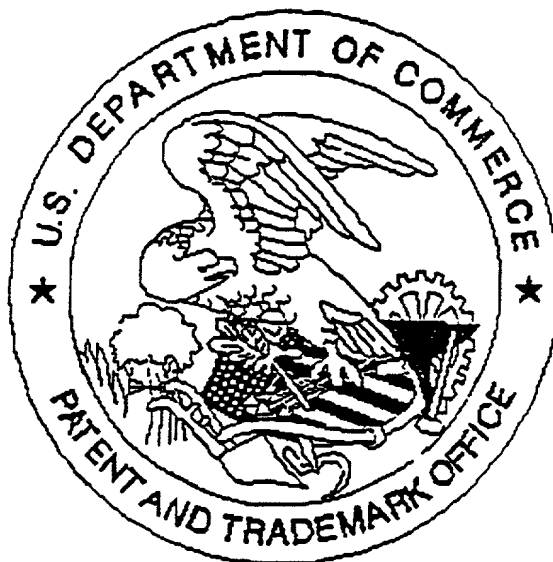


Fig. 4

United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division



Application deficiencies found during scanning:

1. Application papers are not suitable for scanning and are not in compliance with 37 CFR 1.52 because:
 - ☐ All sheets must be the same size and either A4 (21 cm x 29.7 cm) or 8-1/2" x 11" Pages _____ do not meet these requirements.
 - ☐ Papers are not flexible, strong, smooth, non-shiny, durable, and white.
 - ☐ Papers are not typewritten or mechanically printed in permanent ink on one side.
 - ☐ Papers contain improper margins. Each sheet must have a left margin of at least 2.5 cm (1") and top, bottom and right margins of at least 2.0 cm (3/4").
 - ☐ Papers contain hand lettering.
2. Drawings are not in compliance and were not scanned because:
 - ☐ The drawings or copy of drawings are not suitable for electronic reproduction.
 - ☐ All drawings sheets are not the same size. Pages must be either A4 (21 cm x 29.7 cm) or 8-1/2" x 11".
 - ☐ Each sheet must include a top and left margin of at least 2.5 cm (1"), a right margin of at least 1.5 cm (9/16") and a bottom margin of at least 1.0 cm (3/8").
3. Page(s) _____ are not of sufficient clarity, contrast and quality for electronic reproduction.
4. Page(s) _____ are missing.
5. OTHER: No Declarations